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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,492	11/20/2001	Yasuhiro Sando	15162/04190	8558

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EXAMINER

SINES, BRIAN J

ART UNIT PAPER NUMBER

1743

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,492

Applicant(s)

SANDO ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9,12-21 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-9,12-15,17-21 and 24-31 is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

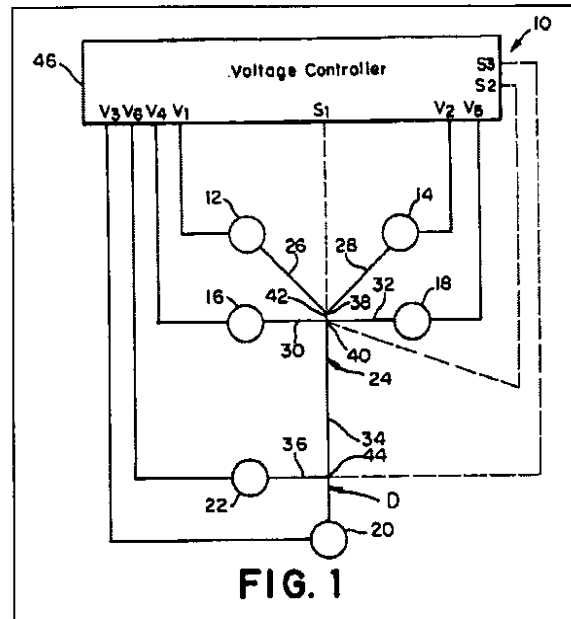
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey (U.S. Pat. No. 5,858,195 A) in view of Bentsen *et al.* (U.S. Pat. No. 6,375,871 B1). Ramsey teaches an apparatus comprising: a first channel or specimen flow pass (*e.g.*, 26); a second channel or reagent flow pass (*e.g.*, 28) in fluid communication with the specimen flow pass; a confluence flow pass (38, 40 & 44); a sensing portion; and a force applying means (*e.g.*, electrokinetic fluid transport *via* voltage controller 46) (see col. 6, line 60 – col. 8, line 20; figures 1 & 30). Ramsey teaches that with laser-induced fluorescence, the point of detection can be placed anywhere along the separation column (see col. 21, lines 33 – 46). Ramsey teaches that the substrate or base of the microchip can be fabricated from a clear material, such as glass, which would be an effective window, and thereby facilitate sample detection using optical methods (see col. 8, lines

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21 – 36). Ramsey teaches that the apparatus comprises a plurality of microchannel branches (26, 28, 30, 32, 34, 36 and 38) (see col. 6, lines 60 – 67; figure 1).



Ramsey does not specifically teach the incorporation of a micropump. Ramsey does teach the use of electrokinetic transport as a pumping mechanism in microfluidic devices (see col. 7, lines 28 – 32). Bentsen *et al.* do teach microfluidic devices having microchannels having vertically tapered inlet and outlet diffusers for piezoelectric valve-less diffuser micropumps for facilitating fluid transport (see col. 4, lines 36 – 48). Both of the disclosed pumping mechanisms are well known in the prior art for being utilized for the same intended purpose, for facilitating fluid transport within microfluidic devices, as evidenced by Bentsen *et al.* and Ramsey. Hence, these pumping mechanisms are considered functional equivalents clearly recognized in the prior art (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the known equivalent pumping

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mechanism, as taught by Bentsen *et al.*, with the microfluidic apparatus of Ramsey in order to facilitate effective fluid transport. Furthermore, the recitation of the flow pass impedance characteristics of the diffusers of the micropump is considered a functional limitation. This claim is drawn to an apparatus statutory class of invention. Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). The Courts have held that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Allowable Subject Matter

Claims 1, 4 – 8, 9, 12 – 15, 17 – 21 and 24 – 31 are allowed.

The following is an examiner's statement of reasons for allowance:

The cited prior art neither teach or fairly suggest the further incorporation within the Ramsey apparatus a micropump which is capable of bi-directional suction and discharge of the specimen sample and the reagent and is provided at a specimen flow pass and the reagent flow

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pass or at the confluence flow pass; and a driver which applies a driving pulse to the micropump to drive the micropump for reciprocating motion. The cited prior art neither teach or fairly suggest the method step of detecting a change in the reciprocal movement due to a reaction of the specimen and the reagent within the flow pass.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

Applicant's arguments and amendments, filed 3/19/2004, with respect to the rejection of claims 1, 4 – 8, 9, 12 – 15, 17, 18 and 20 – 25 have been fully considered and are persuasive. The rejection of claims 1, 4 – 8, 9, 12 – 15, 17, 18 and 20 – 25 has been withdrawn.

Applicant's arguments regarding claim 16, filed 3/19/2004, have been fully considered but they are not persuasive. The applicant argues that Bentsen *et al.* do not teach the flow pass characteristics of the diffusers of the disclosed micropump. However, the recitations of the flow pass impedance characteristics of the diffusers of the micropump are considered functional limitations. A functional limitation is often used in association with an element to define a particular capability or purpose that is served by the recited element, such as the diffusers and micropump in this case (see MPEP § 2173.05(g)). The applicant is advised that this claim is drawn to an apparatus statutory class of invention. Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). The Courts have held

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that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114). Therefore, as the apparatus structure taught by Ramsey in view of Bentsen *et al.* is the same as that structure recited in the claim, the apparatus is capable of performing the same recited function.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700